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Percutaneous Techniques for Endoluminal Carotid Interventions

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Purpose: To describe the evolving techniques for stent implantation in the proximal and cervical carotid arteries.

Methods and Results: Percutaneous access to proximal and cervical carotid lesions is either via direct puncture of the common carotid artery or through the more familiar retrograde common femoral (RCF) artery approach. Both techniques and their variations are described in detail, along with their benefits, disadvantages, and possible complications. Dual lesions at the arch and higher up the neck can be treated either from the RCF route or, if the cervical lesion requires endarterectomy, with open exposure at the bifurcation and stenting of the proximal lesion.

Conclusions: While the RCF route is more familiar to the majority of interventionists and provides adequate access in most situations, traversing the arch and negotiating acute angles at the ostia of the great vessels may render this method infeasible. The direct puncture technique is a useful alternative; however, it requires more expertise to prevent potentially disastrous access-site complications. One further caveat must be stated: regardless of the access approach selected, the opportunity for serious, debilitating—and lethal—complications is always present in cerebrovascular interventions. At this earliest phase in our experience with carotid stenting, cautious investigative methodologies must prevail.

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Key words: balloon angioplasty, stents, carotid occlusive disease, carotid angioplasty

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In the historical development of arteriography for aortic arch and cervical carotid arterial disease, surgeons played a key role by utilizing direct needle puncture of the common carotid and subclavian arteries. Using an 18G needle of varying lengths, the carotid bifurcation, its branches, and the intracranial flow could be visualized with excellent clarity. Similarly, the vertebral origins and the posterior circulations could be displayed via a subclavian approach. As catheter technology advanced and radiographic suites became more sophisticated, surgeons gradually relinquished their position as arteriographers to the diagnostic radiologists. However, the experience gained with the techniques for direct carotid artery access may find another outlet in certain special circumstances, namely, the delivery of stents in the common and internal carotid arteries, cervical carotid bifurcation, and at the aortic arch.

The majority of interventionists, however, will be more familiar and comfortable with the

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retrograde femoral access method, which has almost universally replaced direct carotid stick for angiographic visualization of the arch, cervical, and intracranial arterial systems. This approach has also become most popular for balloon angioplasty and thrombolytic therapy in these arterial distributions, and the same can be said for stent deployment. There are, however, some anatomic considerations that may affect the successful delivery of a stent via this route, situations that do not affect the performance of either angiography or balloon angioplasty.

The great vessels arise from the aortic arch at various angles from oblique to acute. In the latter situation, the sharp angle may cause kinking of the delivery sheath and hinder or obviate stent passage or, occasionally, even delivery of an angioplasty balloon. When confronted with these obstacles, it is advantageous to have the direct stick technique available as a backup so that percutaneous endoluminal therapy can still be applied.

As an elaboration on our recently published initial experiences with our first 110 carotid stent patients,[1] this article outlines in detail the two methods for balloon angioplasty and stent delivery that we have used to treat occlusive disease in the proximal and cervical common carotid artery and its major branches. Each access technique has its own applications, benefits, disadvantages, and complications.

DIRECT CAROTID PUNCTURE TECHNIQUE

Anesthesia

The type of anesthesia selected is entirely the choice of the operator and, to a lesser extent, the patient. One of the main concerns during stent deployment in the cervical carotid area is precise and exact positioning. An uncooperative patient who is frequently moving and even talking creates difficulty with accurate "road mapping" techniques, necessitating more frequent injections of contrast material for proper localization.

In addition, direct puncture of the carotid artery is most easily accomplished when the head is hyperextended, rotated somewhat laterally with elevation of the shoulder on the affected side (Fig. 1). Our experience indicates

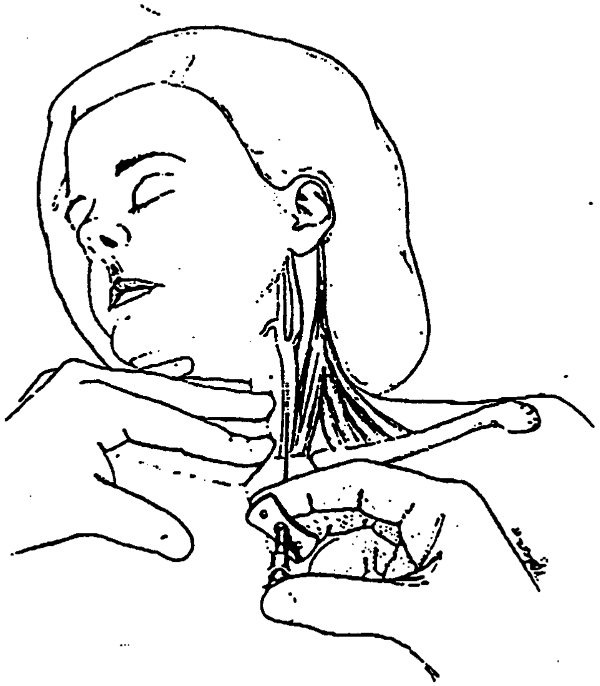

Figure 1 ◆ The desired position of the patient's head for direct carotid puncture is hyperextended and rotated laterally. The shoulder on the treatment side is elevated. This position is best achieved with the patient under general anesthesia.

that this position is best achieved under general anesthesia with the patient intubated. Since we require that the patient be awake and extubated in the endovascular suite immediately following the procedure in order to completely assess neurological status, it is important that short-acting, rapidly reversible drugs be utilized. Details of this anesthetic technique are available elsewhere in this issue.[2]

Other investigators have used cervical block and local anesthesia for balloon angioplasty and stent deployment with satisfactory results.[3,4] In some cases, intubation may not be required; however, we believe it is imperative to have the head and neck completely immobile during the critical points of the procedure. This is quite difficult to accomplish with the anesthesiologist's hand supporting a mask over the patient's face.

Antegrade Common Carotid Artery Access

The patient is prepped and draped similar to a routine carotid endarterectomy with the exception that no towel clips or other radiopaque metal objects are placed in the operative field. Even before prepping, it is a good idea to have the fluoroscopic unit brought over the field to ensure that electrocardiographic lines, intravenous tubing, and other radiopaque objects will not interfere with the imaging. A radiopaque ruler (Burkhart Roentgen, Pinellas Park, FL, USA) is also placed beneath the patient's shoulder at this time, and its position relative to the target carotid artery is confirmed fluoroscopically (Fig. 2). The ruler is helpful for the initial assessment of the lesion and sheath positioning in the anteroposterior view. It is out of the field if a lateral projection is used for angioplasty and stent deployment.

Depending upon the location of the lesion, the entry site into the common carotid artery can be variable distances above the clavicle. If the primary lesion is in the carotid artery below the bifurcation, it is best to achieve as low a puncture as possible in order to allow more free space for the sheath. In most cases, the needle entry is about 2 cm above the clavicle just medial to the sternocleidomastoid muscle (Fig. 1). If the patient's blood pressure is low, palpation of the artery can be enhanced by administration of a vasopressor. For the puncture, our usual preference is an 18G, 2⅜-inch single wall entry needle (Cook, Inc., Bloomington, IN, USA).

Figure 2 ◆ A radiopaque ruler beneath the patient's neck and shoulder facilitates reliable, consistent fluoroscopic identification of the target site.

Occasionally, the carotid artery within its sheath is quite mobile and rolls from side to side as the needle touches it. An instrument has been developed to enhance localization and direct puncture of an artery. The "Smart Needle" (CardioVascular Dynamics, Irvine, CA, USA) (Fig. 3) incorporates a Doppler probe at its distal point. The needle is advanced to the vicinity of the vessel, and as it enters the artery a clear arterial Doppler signal is produced. At times, the needle entry is through the artery, and intraluminal position is confirmed by the Doppler signal as the needle is slowly withdrawn.

A flash of blood from the needle signals entry into the artery followed by a small bolus of contrast to confirm its position. A 0.035-inch

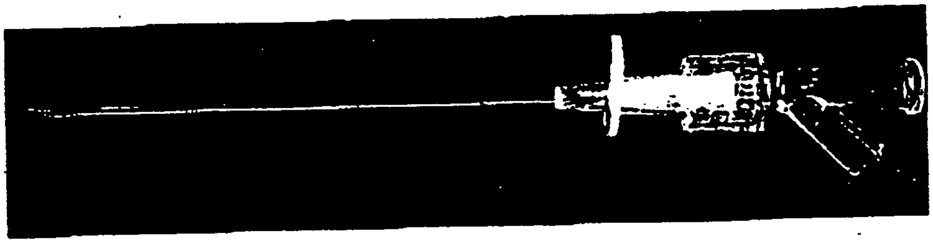

Figure 3 ◆ For difficult arterial access situations, the Smart Needle with its Doppler probe incorporated in the distal tip may be useful in documenting arterial entry.

(0.89-mm), 80-cm, angled hydrophilic guidewire (Glidewire, Medi-tech/Boston Scientific Corp., Watertown, MA, USA) is introduced and, for an antegrade approach to distal lesions, passed cephalad into the external carotid artery (ECA) (Fig. 4). Movement of the wire across the internal carotid artery (ICA) is avoided in order to reduce embolic complications. A small nick is made in the skin around the wire (this can be done prior to needle puncture if desired). Frequently, there is some resistance to sheath entry, especially in patients with thick necks; therefore, a 7F Coons dilator (Cook, Inc.) may be used in order to expedite the sheath placement (Fig. 5). A 7F, 6-cm-long sheath (Cordis, Miami Lakes, FL, USA) is inserted (Fig. 6). Again, a short bolus of contrast confirms sheath placement, and a fluoroscopic road map is acquired on the disk. From this point on, the fluoroscopic unit remains stationary. Three to five thousand units of heparin sodium are given intravenously to maintain the activated coagulation time (ACT) above 250 seconds, and the sheaths and catheters are irrigated with a heparinized saline solution (10,000 units of heparin to 1000 cc normal saline).

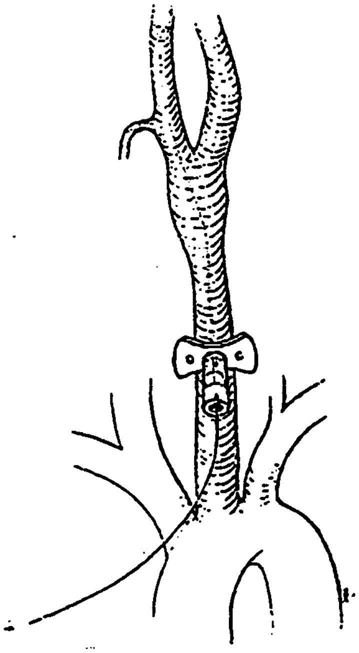

Figure 4 ◆ Positioning of the guidewire in the external carotid artery after arterial access is achieved.

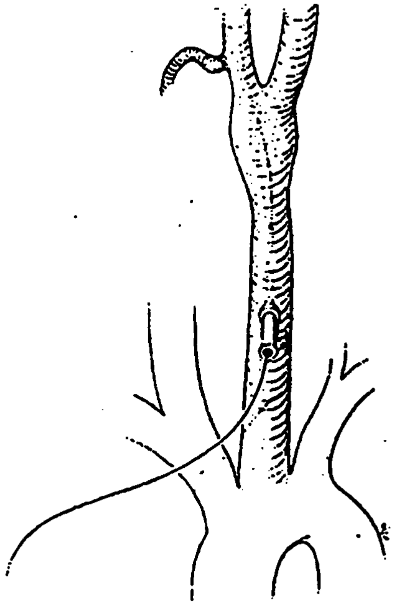

Figure 5 ◆ If resistance to the sheath is encountered, a Coons dilator may be used to facilitate sheath introduction.

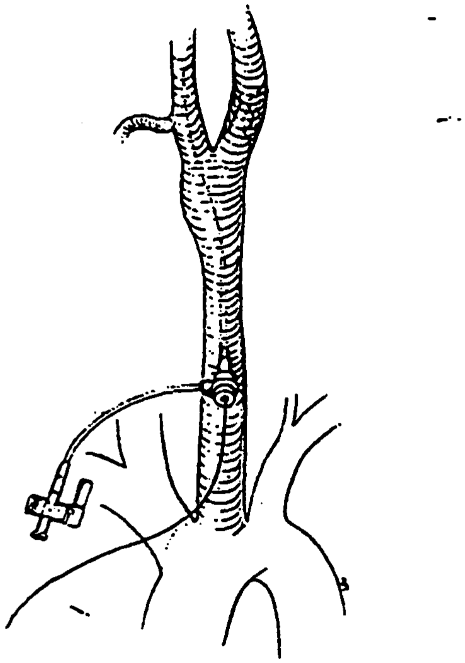

Figure 6 ◆ A 6-cm, 7F sheath is commonly used for antegrade carotid interventions.

The length and diameter of the lesion are then judged. While some investigators use direct measurements from the fluoroscopic image, we have found this technique to be unnecessary and rely on direct visualization as we do in other anatomic locations.

At this point, two options exist, and there is still considerable discussion about which is preferable. If the lesion is severely stenotic, we prefer to use balloon dilation initially, followed by stent deployment. The major reason for this sequence is to avoid possible stent movement on the balloon if it is passed across a highly stenotic lesion.

At the present time, there are no balloon delivery systems that hold the stent securely until deployment. This is not of great consequence in the iliac, superficial femoral, or other arterial locations, but in the cervical carotid area, displacement, dislodgment, or loss of a stent could create a catastrophe. For this reason, unless the lumen of the affected vessel is < 70% stenosed, as it might be in cases of ulceration, we prefer to predilate with a small balloon, thereby assuring easy passage of the stent. Preprocedural duplex scanning is extremely valuable in assessing the nature of the lesion and the degree of narrowing. Usually the diameter of this predilation balloon is at least one or two sizes smaller than the stent delivery balloon (e.g., Medi-tech's 40-cm PEMT: 4- to 8-mm × 2-cm; Cook's 40-cm Accent: 4- to 8-mm × 2-cm).

In order to shorten the interval between balloon predilation and stent deployment, a period in which the artery is at least partially disrupted from the effects of the dilation, the stent delivery balloon is prepared prior to the initial dilation. This is accomplished by manually pressing the stent over the balloon, assuring that no movement of the stent is possible as it passes through the guiding catheter (Fig. 7).

Selection of the appropriately sized stent is based upon the diameter and length of the lesion. In our experience, the most common balloon dilation catheter is a 5-mm × 2-cm balloon followed by stent delivery on the same sized or the next larger balloon. We routinely use a fresh balloon for stent delivery in the event the angioplasty balloon develops a leak that prevents proper stent expansion. While

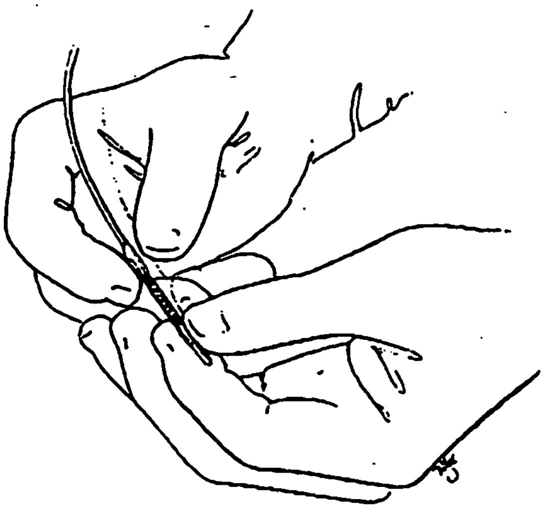

Figure 7 ◆ The stent delivery balloon is prepared in advance of the initial dilation by manually pressing the stent over the balloon. The stent must be securely crimped onto the balloon to prevent movement as the stent passes through the guiding catheter.

this is just our precautionary preference, it is possible to use the same balloon and even leave the stent already mounted on the shaft for rapid delivery (Fig. 8). Palmaz stents (Johnson & Johnson Interventional Systems Co., Warren, NJ, USA) ranging from 10 to 30 mm in length (models P104, P154, P204, and P294) are our preference. The longer stents are deployed more frequently in common carotid or longer lesions across the bifurcation.

Once the balloon and stent have been selected and prepared, the guidewire is withdrawn from the ECA and passed across the lesion into the ICA. Every attempt is made to keep the wire as low in the extracranial ICA as possible to avoid any vascular trauma or arterial spasm.

At this point in the procedure, it is important that the anesthesiologist administer atropine (0.5 mg). As surgeons know from their experience operating at the carotid bifurcation, the baroreceptors are extremely sensitive to manipulation, and particularly dilation. Atropine at least partially blocks the undesired bradycardia and hypotension that frequently occur at the time of balloon expansion. Some investigators have suggested the routine use of a temporary pacing wire.[5] We have not found this precaution necessary.

The balloon is then centered across the lesion based on the road map image. Since there is always a possibility that movement may have occurred at some time up to this point, a short burst of contrast is injected to assure final accurate positioning. The balloon is expanded for 10 to 15 seconds at 12 atm (Fig. 9), and if bradycardia occurs, it is quickly deflated. The shaft of the angioplasty catheter is rotated to furl the deflated balloon before it is retracted. A contrast injection confirms the result

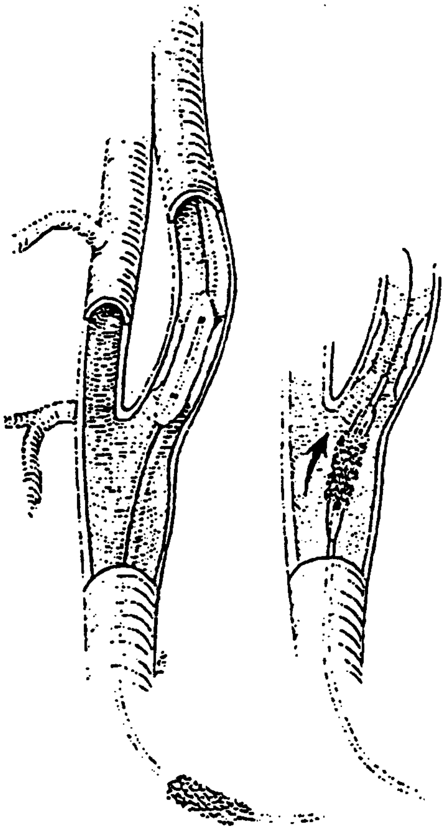

Figure 8 ◆ If the original angioplasty balloon is to be used for stent delivery, the stent can be threaded onto the shaft before the initial dilation to expedite mounting.

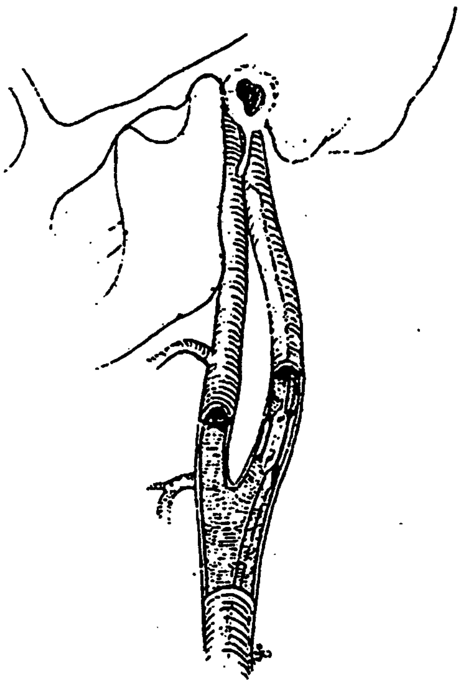

Figure 9 ◆ Between 10 and 15 seconds of balloon inflation at 12 atm is usually sufficient for preparatory dilation of the carotid lesion.

of the balloon dilation, which is often not satisfactory.

The stent/balloon catheter is then advanced into position. At this time, it is essential to confirm that the stent is properly situated between the dots on the balloon. If there has been any movement or misalignment, the stent should be repositioned, even if it requires complete removal of the balloon/stent delivery catheter.

When the operator is satisfied with the stent's position, the balloon is expanded to deploy the device (Fig. 10). Again, only a short period of 5 seconds is needed for balloon expansion, and as during the initial dilation, the electrocardiogram should be carefully monitored.

Following stent deployment, contrast is injected to confirm patency and assess proper positioning. We routinely use real-time intravascular ultrasound (IVUS) imaging at this point in the procedure. Our experience in other arterial locations has confirmed that the control angiogram alone is not sufficient to assess proper stent deployment.[6,7] This appeared to be particularly true in our initial carotid series, where oftentimes the diameter of the stented artery at its cephalic and caudal ends was considerably different.

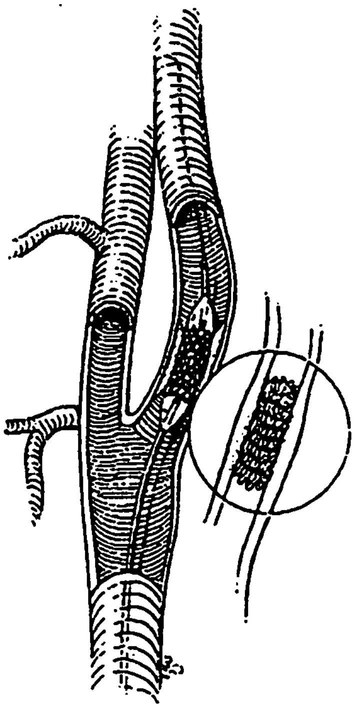

Figure 10 ◆ When exact positioning of the stent is confirmed, the delivery balloon is inflated for approximately 5 seconds to deploy the device.

The IVUS catheters currently available for this application require a 0.018-inch wire (e.g., a nitinol wire [Microvena Corp., White Bear Lake, MN, USA] or a Platinum Plus [Meditech]) in a monorail configuration. The stent delivery balloon is used to perform the wire exchange prior to its removal after stent deployment. The IVUS catheter (3.5F, 140-cm, 30-MHz Sonicath [Medi-tech]) (Fig. 11) is introduced into the ICA, and a "pull through" from the internal to common carotid artery is performed (Fig. 12A, upper left insert). These images are acquired in both two-dimensional (Fig. 12A, right) and three-dimensional formats, permitting precise assessment of stent deployment. Measurements of the artery and stent diameter are made from the IVUS image (Fig. 12B), and if the stent is not in complete apposition with the arterial wall at any point, a larger balloon is selected and the condition corrected. The angiograms and IVUS assessment are repeated for confirmation of satisfactory deployment.

The ACT is determined after the completion studies and, if necessary, corrected to the range of 125 to 145 seconds by the administration of protamine sulfate. The sheath is then removed, and direct pressure is applied over the puncture site for a 15-minute period.

When the puncture site is completely sealed, anesthesia is discontinued. It is important to monitor blood pressure closely at this time to prevent hypertension that would contribute to hematoma formation at the puncture site.

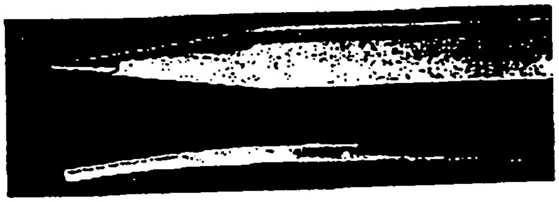

Figure 11 ◆ A 3.5F intravascular ultrasound probe should be among the monitoring equipment used for carotid angioplasty. IVUS interrogation is mandatory for accurate stent placement.

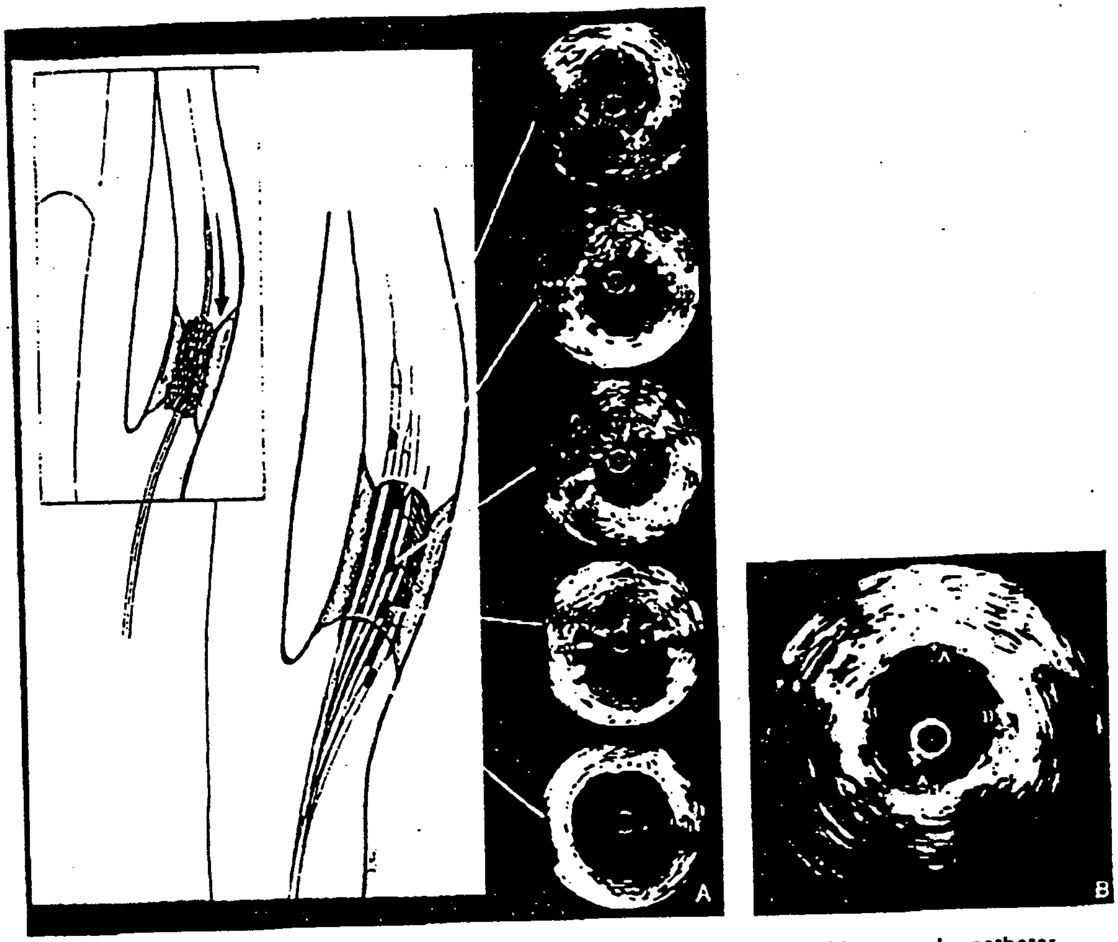

Figure 12 ◆ (A) With the IVUS catheter introduced into the internal carotid artery, the catheter is pulled back through the stent into the common carotid artery. Two-dimensional images are acquired at strategic points along the length of the treated segment. The upper and lower images show normal artery above and below the stent. The three central views demonstrate the stent, which at its cephalad end is well deployed. As the IVUS probe moves down the stent, however, the presence of calcification (middle image) has prevented the stent from expanding fully. At its caudad end, the bright echoes of the struts indicate that the stent is not well apposed to the vessel wall at this point. (B) Measurements of the artery and stent diameter are made from the IVUS image, and if the stent is not in complete apposition with the arterial wall, further dilation is necessary.

Likewise, when the patient is extubated, care should be exercised to avoid coughing and retching. It is usually a good idea to continue compression over the neck during this phase as a preventive measure. A pressure dressing is then applied over the puncture site. The patient is awakened fully and assessed for any neurological deficits prior to transfer to the intensive care unit, where a duplex scan of the treatment site is performed within the first hour (Fig. 13).

Retrograde Common Carotid Artery Approach

Lesions in the mid and proximal portion of the common carotid artery cannot be ap-

Figure 13 ◆ Example of a duplex scan performed within 1 hour after treatment showing normal flow through the fully deployed stent (intermittent bright echoes are the stent struts).

proached by a direct antegrade entry. There is insufficient space for sheath insertion for the mid carotid lesions, and those at the arch would be well below the puncture site. Under these circumstances, a retrograde approach provides easy access for stent deployment. The aspects of this approach are identical to the antegrade technique except in the opposite direction.

The needle entry site is in the upper third of the cervical carotid artery (Fig. 14), and a 7F sheath is inserted. The side port of the sheath can be attached to a pressure transducer for measurement of the pressure gradient across the proximal lesion (Fig. 15). Dilation, stent deployment, and IVUS assessment follow as described previously. Because the carotid artery in this location is usually 7 to 9 mm in diameter, larger balloons and the 30-mm (P294) Palmaz stents are more commonly used. Eradication of the pressure gradient is seen following successful stent deployment (Fig. 15). Removal of the sheath and postprocedural control are similar to the antegrade approach.

Dual occlusive lesions involving both the most proximal and cervical portions of the common carotid artery can be approached in one of two ways. If the cervical lesion is amenable to stent therapy,[8] both proximal and cervical carotid lesions may be accessed from a retrograde femoral approach (see below).

On the other hand, if the cervical lesion requires endarterectomy, the most efficient way to treat both lesions simultaneously is with open exposure of the carotid bifurcation. Just below the intended arteriotomy site in the common carotid artery, the retrograde technique is used before opening the artery. The needle, wire, and sheath are inserted directly, pressure gradients are measured, and dilation and stent deployment are accomplished as described previously. After proximal stent deployment, the sheath is removed and a standard endarterectomy of the bifurcation performed (Fig. 16) with or without patch graft angioplasty, depending on the indication.

This combined technique can be used on either the left carotid system or the right, where the proximal stent may be deployed at the carotid artery orifice on the brachiocephalic artery or more proximally should the lesion extend to the arch.

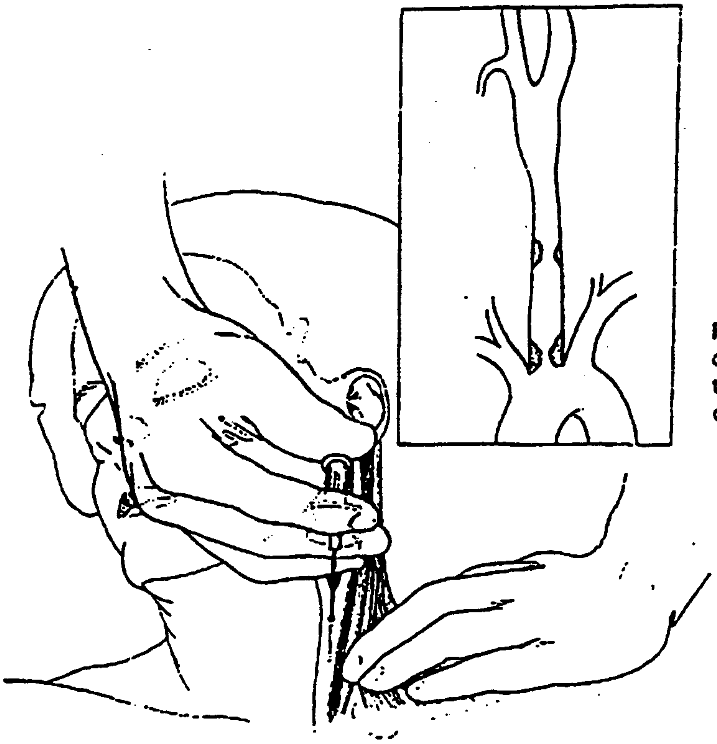

Figure 14 ◆ For the retrograde common carotid approach to proximal lesions, the needle entry site is in the upper third of the cervical carotid artery.

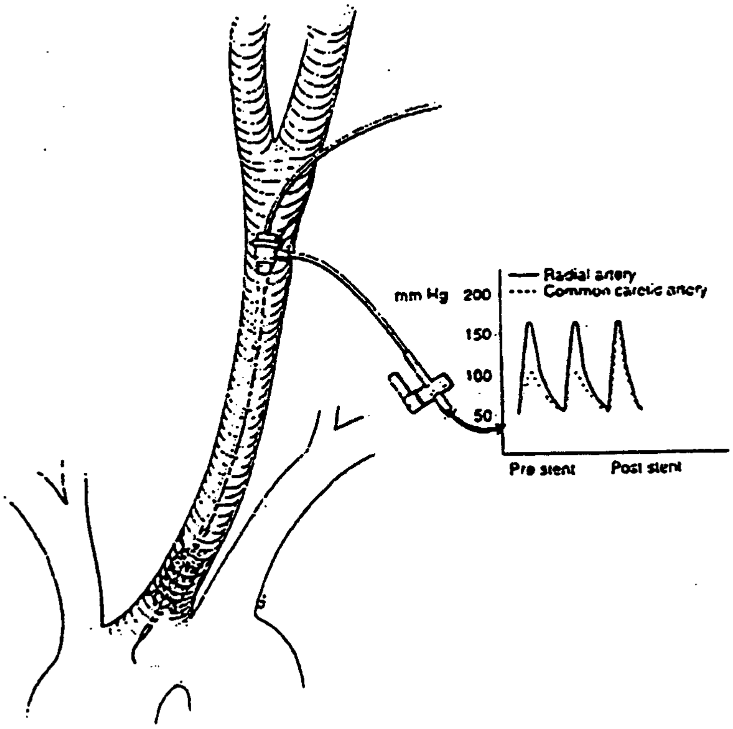

Figure 15 ◆ Pressure gradient measurement is an important monitoring tool in all angioplasty procedures. For this proximal common carotid lesion, stent deployment has satisfactorily abolished the pretreatment gradient between the carotid and radial arteries.

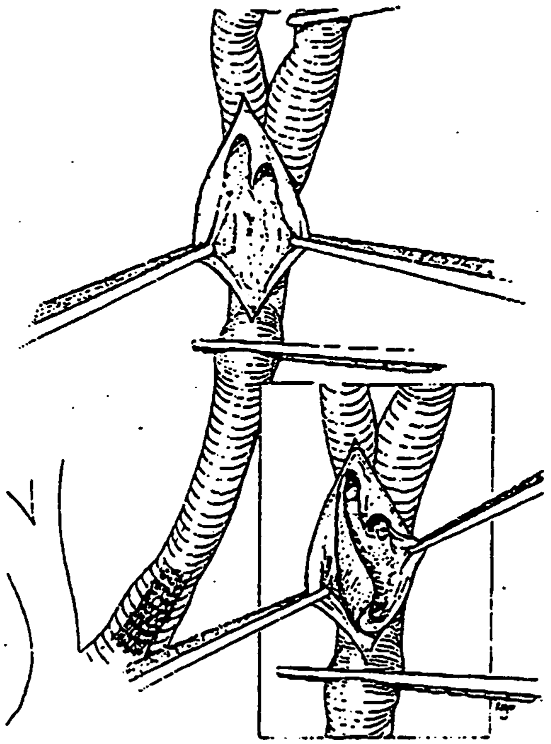

Figure 16 ◆ In a patient with proximal and bifurcation lesions, it is most efficient to treat them simultaneously with open exposure of the bifurcation. The arch lesion is addressed first by directly inserting the needle, wire, sheath, and catheters. Once the stent is deployed and the sheath removed, endarterectomy of the bifurcation lesion can ensue.

Complications

With these direct access techniques, complications are related almost exclusively to sheath insertion, removal, and hemostasis at the puncture site. Balloon dilation, wire manipulation, and stent deployment are accomplished quite easily owing to the short distance between the entry site and the target lesion. This is in contrast to the retrograde femoral approach where long catheters and more extensive manipulation are required. In the patient with a thick neck, there may be a tendency for the sheath to kink, and care must be taken when the catheter and stent delivery system are passed through the sheath. We have encountered one patient in whom the procedure had to be abandoned because of this complication.

More important is the potential for hematoma formation with sheath removal. The puncture site compression technique described above is a satisfactory method to prevent this complication, but close cooperation with the anesthesiologist is essential. This was borne out in our experience when the senior operator allowed a less experienced associate to handle sheath removal and puncture site control. The patient awoke with extreme coughing and hypertension. A large hematoma resulted, demanding immediate evacuation and control of bleeding. Unfortunately, this patient suffered a neurological complication. Extreme care and coordination can avoid this problem.

PERCUTANEOUS RETROGRADE FEMORAL ARTERY APPROACH

Anesthesia

The preferred anesthesia for this approach is local with mild sedation. We have found it reassuring to be able to communicate with the patient throughout the procedure, thereby assessing immediately any neurological change. Our anesthesiologists have developed a technique that provides the patient with complete comfort while, at the same time, remaining completely conversant.[2]

Artery Access

The common femoral artery to be used for access is selected based on the condition of the iliac artery. Because a sheath or guiding catheter will be passed into the aortic arch, the side with the less tortuous and stenotic iliac artery is chosen. An 18G, 2⅞-inch needle is inserted followed by a 0.035-inch guidewire (Glidewire, Medi-tech) and 9F sheath (Cordis). A 260-cm, 0.035-inch angled hydrophilic guidewire (Medi-tech) is passed into the aortic arch, and a JB2 catheter (Cook, Inc.) is passed into the high ascending aorta. The wire is withdrawn a sufficient length to expose the angle of the JB2 catheter, which is then slowly pulled back to selectively engage either the brachiocephalic trunk or the origin of the left common carotid artery (Fig. 17).

The angled guidewire is passed into the appropriate carotid artery, and the JB2 catheter

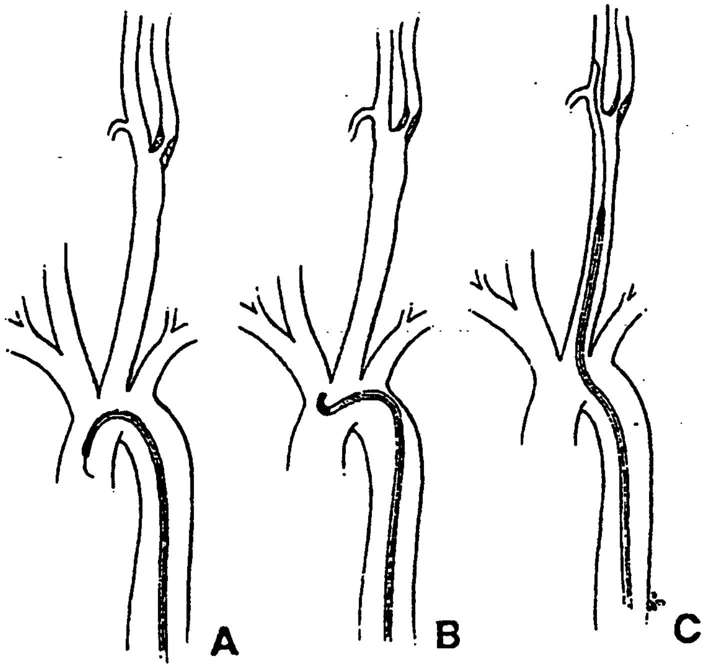

Figure 17 ◆ To selectively engage either the brachiocephalic trunk or the origin of the left common carotid artery, a JB2 catheter is passed into the high ascending aorta (A). The wire is withdrawn a sufficient length (B) to expose the angle of the catheter for manipulation into the vessel of choice (C).

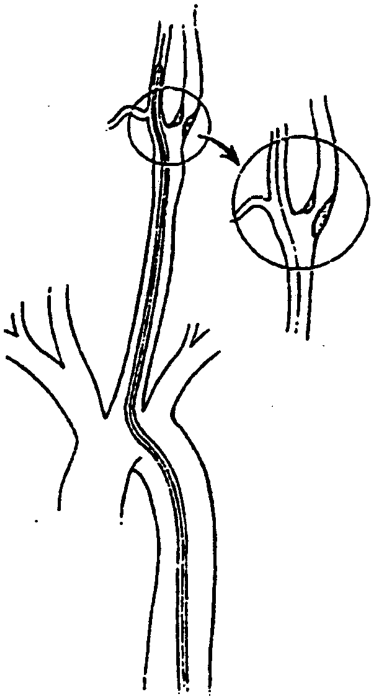

Figure 18 ◆ The angled guidewire is passed into the external carotid artery followed by the JB2 catheter to prevent having a wire across the lesion during insertion of the delivery sheath.

is advanced over it to about the mid level of the carotid artery. The wire is withdrawn, and a small bolus of contrast is injected to secure a road mapping image. The angled guidewire is then passed into the ECA followed by the JB2 catheter (Fig. 18). This maneuver is accomplished to prevent having a wire across the lesion during insertion of the delivery sheath. The guidewire is removed and replaced with a 260-cm Super Stiff Amplatz wire (Cook, Inc.), which is passed into the ECA. The JB2 catheter is withdrawn, and the fluoroscope is panned from the cervical carotid artery across the arch to assess the angle and origin of the great vessel to be traversed by the delivery catheter (Fig. 19). Too acute an angle at the carotid artery junction can produce kinking in the delivery sheath (Fig. 20) and require conversion to the direct stick approach.

Depending on the angle of the wire and the degree of bending at the aortic arch, a delivery catheter (Cook, Inc.) is selected from among several multipurpose designs for the balloon

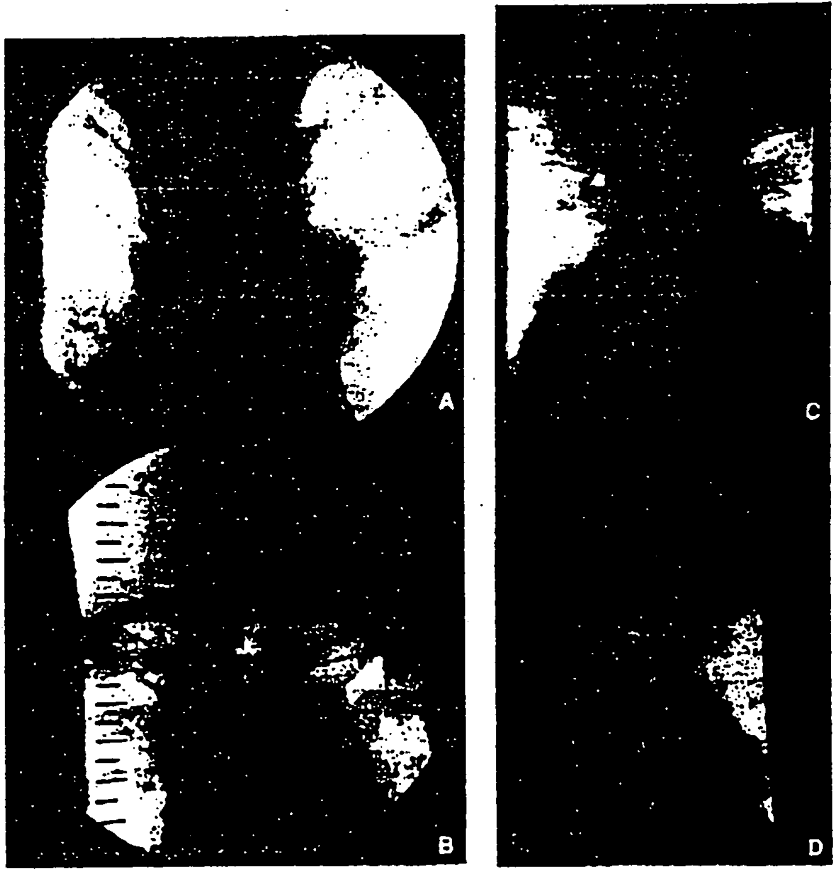

Figure 19 ◆ (A) A fluoroscopic image showing the wire across the aortic arch into the right common carotid artery. An H1 Cook delivery sheath (see Fig. 26) would be selected for balloon and stent delivery. (B) This fluoroscopic image offers an example of an acute angle at the aortic arch that may preclude successful stent passage. (C) The wire in this left common carotid artery has an almost 90° bend at the aortic arch. Again, a nonflexible stent would probably not traverse this angle. (D) The smooth curve of this wire into the left carotid artery could be negotiated with an MBF1 Cook multipurpose delivery catheter.

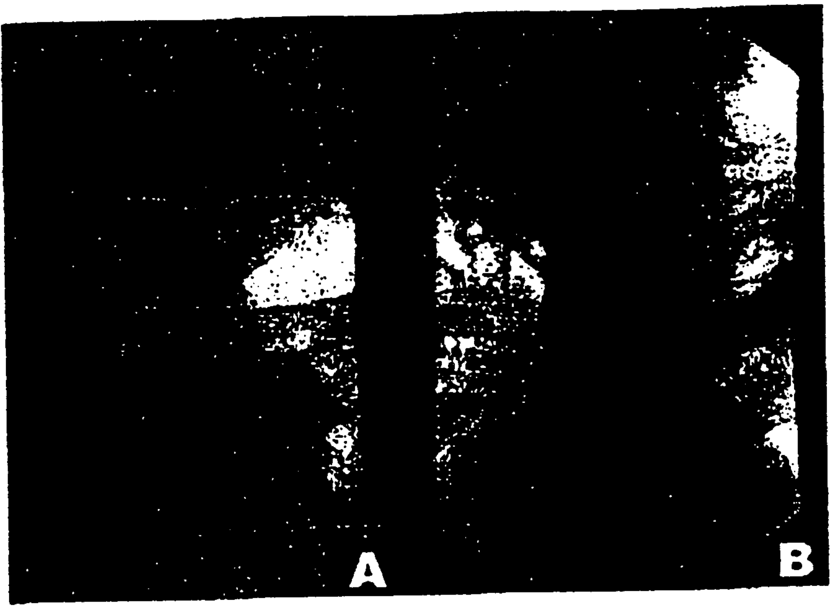

Figure 20 ◆ The anatomy of the arch vessels is an important consideration in retrograde femoral stent delivery. A sharp bend in the common carotid artery (A) or too acute an angle at the arch (B) may cause kinking of the delivery sheath, requiring conversion to the direct stick approach.

and stent deployment. The delivery sheath is passed into the mid carotid position, and intravenous heparin is administered. Then either an Amplatz Super Stiff wire or angled guidewire is positioned across the lesion in the ICA (Fig. 21). If the Amplatz is selected, its positioning usually requires a wire exchange using an angled guidewire and guiding catheter. Contrast is injected to obtain a road map image to determine the dimensions of the artery and the nature and length of the lesion. An appropriately sized balloon is selected for predilation, usually a 4- or 5-mm × 2-cm balloon with a 120-cm shaft length. At the same time, a stent is chosen and mounted on another balloon in preparation for delivery.

The predilation balloon is passed to the lesion, and after confirmation that atropine has been administered, the balloon is inflated for 10 to 15 seconds at 12 atm. A small bolus of contrast is injected to assess the angioplasty result. The balloon with stent is then passed to the lesion, and a second contrast injection is used to confirm the proper location since patient movement is always a possibility. The stent is deployed with a 5-second balloon inflation (Fig. 22).

The balloon catheter is used for a wire exchange in order to accommodate the 0.018-inch wire for the IVUS catheter. If the IVUS analysis confirms perfect deployment, a final control angiogram is performed. On the other hand, if the IVUS image indicates incomplete stent deployment, additional dilation with larger balloon(s) should be undertaken until stent-wall apposition is adequate throughout.

The guiding catheter is then withdrawn and substituted for a short 9F sheath in the groin. The patient is transferred to the intensive care unit for observation and duplex scanning. When the ACT has returned to normal, the groin sheath is removed.

Complications

Aside from the usual potential problems that may accompany any femoral access (hematoma, pseudoaneurysm, bleeding, etc.), the only other difficulty we have encountered is the inability to deliver the stent in anatomically

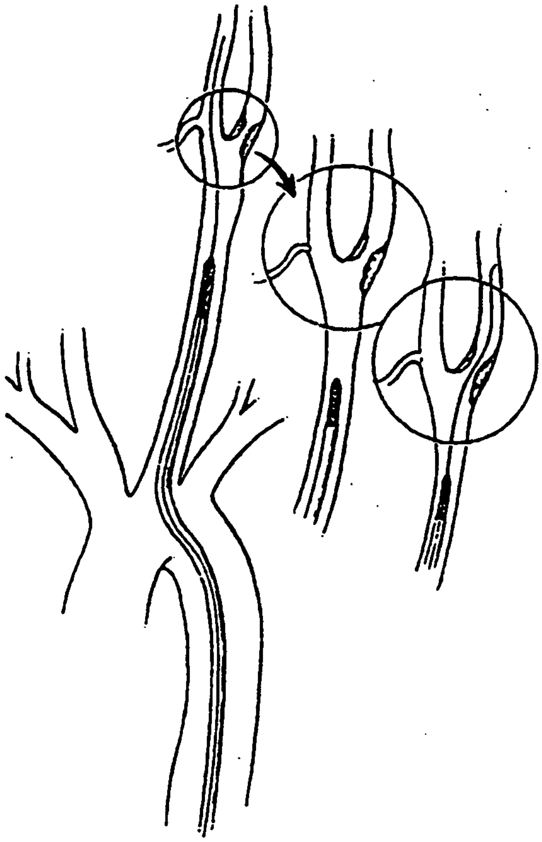

Figure 21 ◆ If the arch anatomy is suitable, the delivery catheter is passed into the mid carotid position, and the guidewire is directed across the internal carotid lesion.

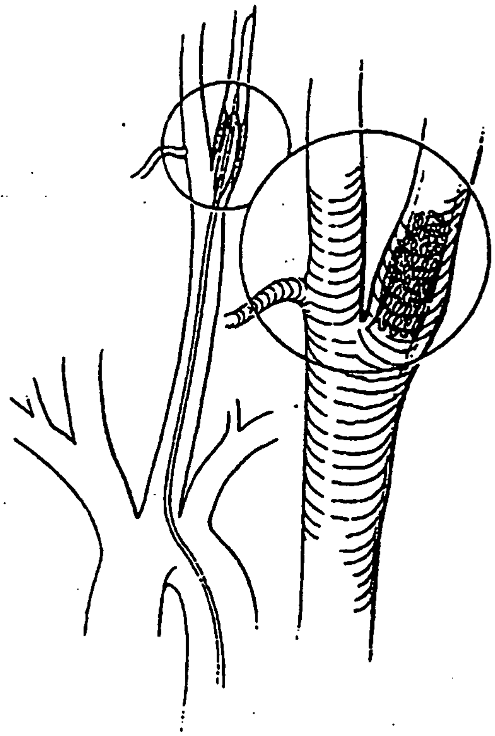

Figure 22 ◆ After confirmation of exact stent position, the balloon is inflated for 5 seconds to deploy the device in the internal carotid artery.

unfavorable situations. Having the ability to switch to the direct carotid puncture method can save the patient from conversion to an open endarterectomy procedure.

POSTPROCEDURAL CARE

All carotid stent patients are placed on antiplatelet therapy (aspirin only) prior to treatment; this is resumed the day following the procedure. No postprocedural anticoagulation is used. Neurological changes are reported immediately, initiating neurology consultation and appropriate studies; computed tomography (CT) is scheduled to assess any suspected embolic event. The majority of the patients are discharged the day following the procedure.

DISCUSSION

There are several critical issues that should be discussed with regard to the currently applied techniques for carotid stent deployment. First is the selection of the access approach. In our early experience, we preferred the direct stick approach. We had considerable experience in this method, and we were confident that it afforded quick access that would accommodate the then available (in 1993) catheters and sheaths with which we were familiar. Another assumption was that the alacrity of this approach and the short balloon expansion times would obviate the need for heparinization, so our first 28 patients were unheparinized. We were also of the opinion that maintaining a normal coagulation profile would reduce bleeding complications.

Unfortunately, most of these assumptions proved wrong. Our early cases were plagued by complications related to the access method. Three patients developed hematoma (3/28 [11%]) and neurological symptoms (1 stroke and 2 transient ischemic attacks [TIAs]). One of the stents occluded as well. Another patient developed an arteriovenous fistula that required operative repair. Two other patients who developed TIAs were converted to carotid endarterectomy; thrombotic material was found on the interstices of the stents. In follow-up, two more stents implanted in this early unheparinized group suffered early (< 2 months) occlusion.

As these events began to unfold, we made changes in our technique. Notable among these were the use of systemic heparinization and more scrupulous attention to factors influencing puncture site hemostasis. Following one iatrogenic hematoma case, we henceforth allowed only well-trained operators to manage the carotid puncture site. Working closely with the anesthesiologist, who monitors blood pressure to avoid hypertension, the physician must maintain adequate pressure on the wound as the patient is awakened and extubated gently to avoid coughing.

Once long-shafted balloons and sheaths were available, we began using the retrograde femoral route preferentially. While this approach prevented cervical access-related complications, it was not mechanically suitable for stent delivery in all patients. The variable anatomy of the aortic arch vessels both at their ostia and throughout their infraclavicular course can make manipulation of the stent-bearing balloons impossible. We found this in several patients, and we converted to the direct approach to circumvent this problem.

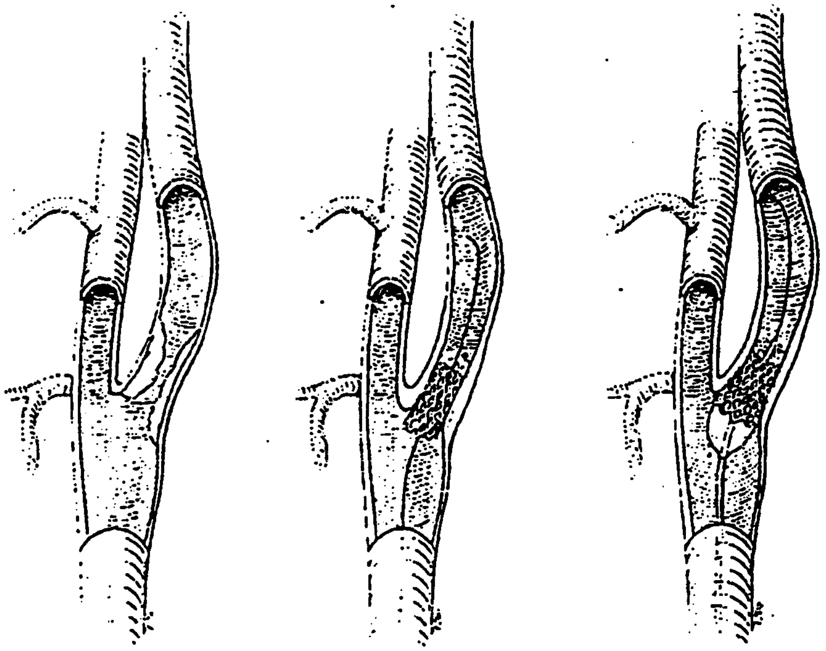

Figure 23 ◆ When disease in the internal carotid artery extends into the common carotid (left), the caudad end of the stent will overhang the ICA orifice (middle). Achieving satisfactory apposition of the entire stent at this location may require "trumpeting" the caudad end of the stent with a short balloon (right) to overcome the size differential between the internal and common carotid vessels.

Another technical enhancement that has proved invaluable was the introduction of IVUS imaging. During our first 25 cases, we used completion arteriography alone to evaluate stent deployment. Now that we have done more than 150 stent deployments with IVUS monitoring, we believe that inadequate stent expansion contributed to many of our early complications, notably stent occlusion and thrombus formation. It may even have played some role in the microembolization process that precipitated neurological sequelae.

Today, we use real-time IVUS imaging in both the two-dimensional mode and with three-dimensional reconstruction. Several points are of critical importance in reviewing these IVUS images. We examine the length of the treated site for any signs of dissection of the artery above the stent. We encountered such a case once, in which the angiogram failed to identify the defect. IVUS identified the dissection and directed the deployment of another stent to re-establish a smooth lumen.

One obviously important factor is stent apposition with the artery wall. Given the arterial location and the vulnerability of the end organ it serves, we believe that optimal stent expansion is more crucial in the carotid system than in any other peripheral location. Any stent must be firmly embedded against the carotid arterial wall to preclude movement that could elicit embolization or create turbulent flow and precipitate thrombus formation.

Another anatomical feature of the carotid system is the discrepancy in diameters between the common carotid artery and its internal and external branches. Any ICA or ECA stent that is placed with its caudad terminus in the common carotid artery must be expanded segmentally with short balloons to counteract the arterial wall differential. IVUS is particularly useful in directing the need for and extent of this maneuver.

In this regard, however, we must add a special note. It is well known that as a stent is further dilated after its initial deployment, it not only expands in diameter but also shortens in length. Additionally, the interstices of the stent change their configuration and, in particular, widen. These consequences of what we might call secondary balloon expansion may produce no adverse effects, and in our aortic and iliac experience, we have performed this specific maneuver on numerous occasions. However, in the carotid location, there may well be a serious, unacknowledged sequel to further stent expansion. Granted, it certainly seems unwise to leave a stent that is not in perfect apposition with the arterial wall, particularly if it is "hanging" in the common carotid artery (Fig. 23). On the other hand, as the stent is expanded and it shortens, there may be a shearing effect on the atherosclerotic plaque. This, coupled with the enlarging interstices, may provide an opportunity for the atherosclerotic debris to be exposed to the open bloodstream, with resultant embolization (Fig. 24). We have encountered at least one such case in which

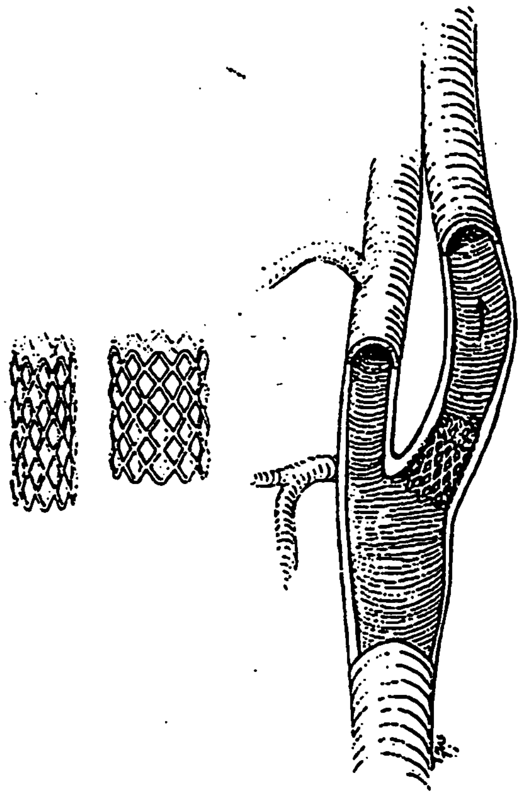

Figure 24 ◆ Expanding a stent to its maximum diameter increases the size of the interstices (left). This, coupled with the shearing effect on the plaque produced by the shortening of the stent as it expands, may loosen and/or expose atherosclerotic debris to the bloodstream with consequent embolization (right).

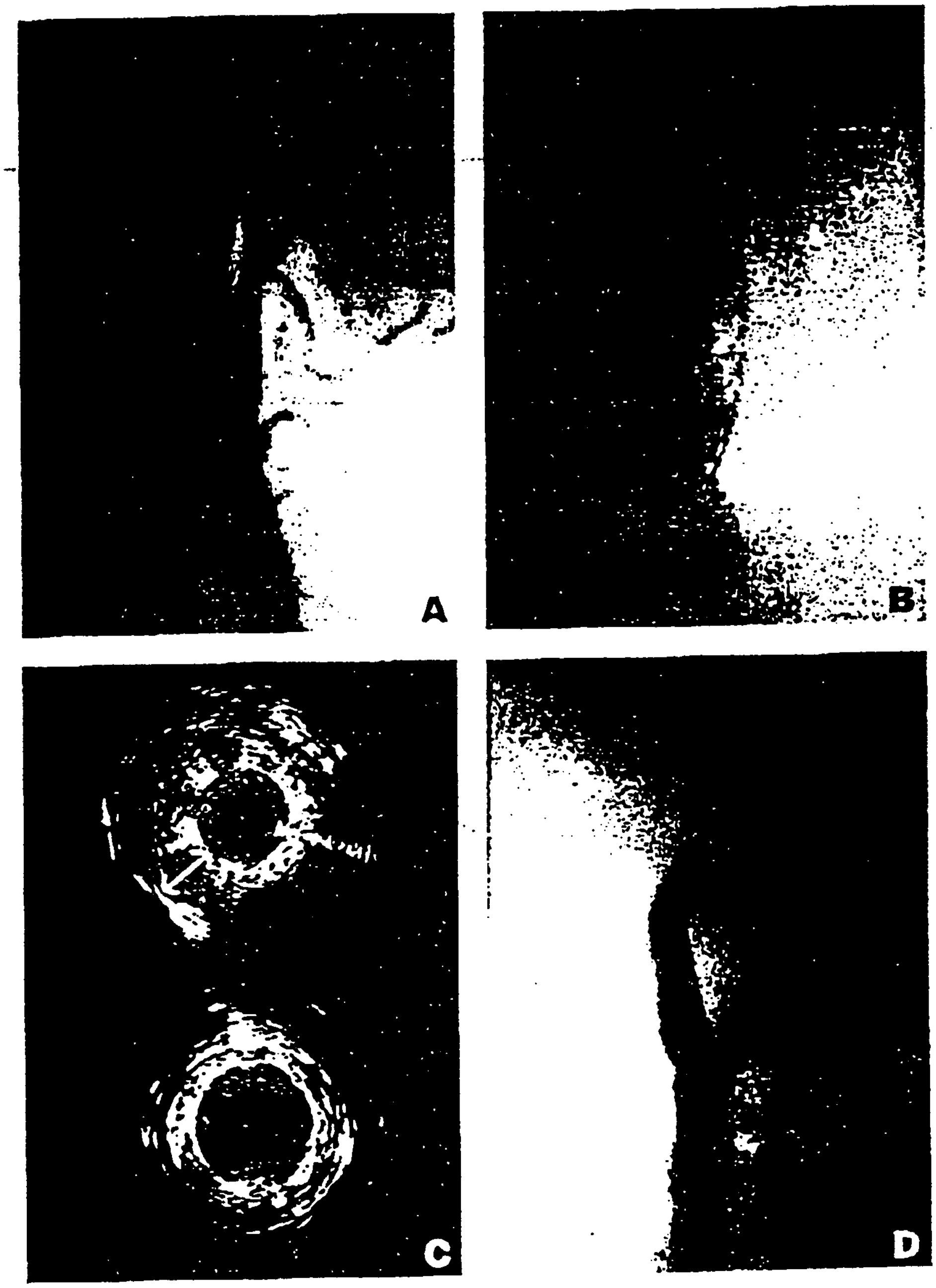

Figure 25 ◆ (A) This 70% left ICA stenosis extending into the common carotid artery was treated with a Palmaz P294 stent (B) that protruded into the bifurcation. IVUS imaging (C) showed inadequate expansion in the stent's mid section (arrow), so further dilation was performed. The final result (D) was excellent; however, 1-hour postprocedure the patient experienced aphasia and right-sided weakness. A CT scan confirmed a left nonhemispheric infarct in the distribution of the middle cerebral artery (MCA), but no stent thrombosis or MCA occlusion was detected on postprocedural arteriography. The patient's symptoms resolved within 6 weeks.

our eagerness to assure a perfect IVUS result clearly created this unusual consequence (Fig. 25). Present work on covered stents may in the future obviate this complication.

Insofar as equipment is concerned, there are a few points that are noteworthy. We have been interested in developing a delivery catheter with a hemostatic valve that, when positioned, would permit contrast injection for repeated assessment, as well as passage of the stent/balloon assembly across the aortic arch into the cervical carotid artery. Four different shapes are being evaluated (Fig. 26); the multipurpose MBF1 and the H1 are the most commonly used at the present time. The catheters are 85-cm long and come in both 9F and 10F sizes (Cook, Inc.). They track over the Amplatz wire smoothly into the carotid artery and have a distal radiopaque marker that is ideal for catheter localization (Fig. 27). The single problem that has been encountered relates to acute angles at the aortic arch, which these catheters may not negotiate well. The catheter material may still be more flexible than desired, and modifications incorporating a stiffer material are being considered.

Selection of predilation and delivery balloons are at the discretion of the operator;

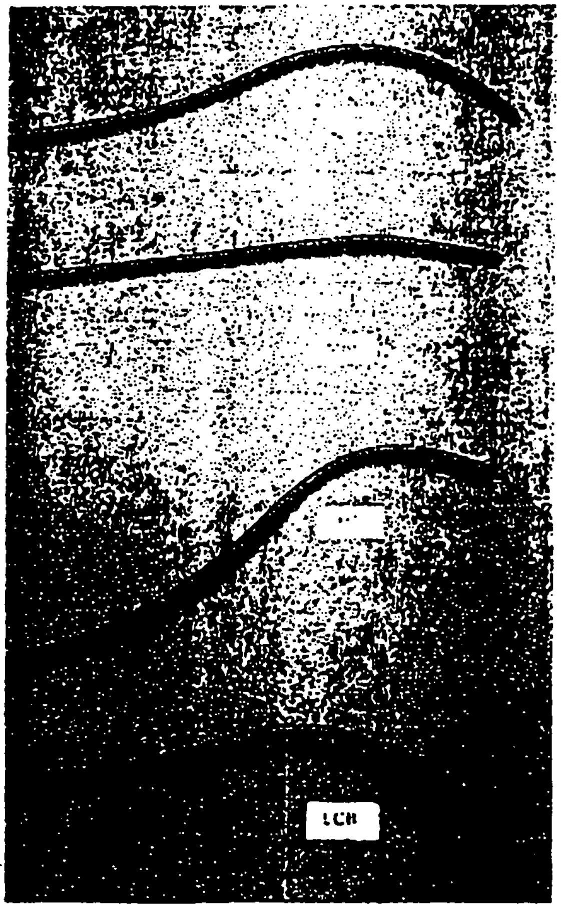

Figure 26 ◆ Four different styles of Cook multipurpose delivery catheters (9F and 10F; 85-cm long) are being evaluated for use in carotid stenting. The MBF1 and the H1 are the most commonly used at present.

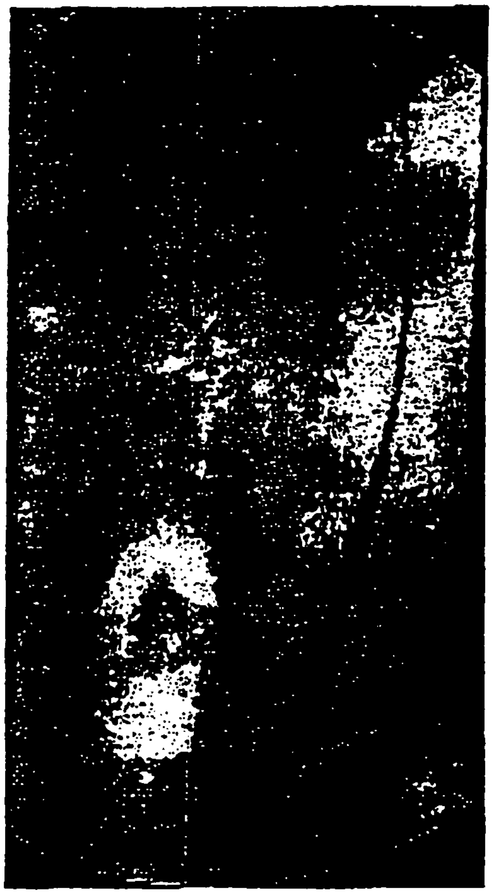

Figure 27 ◆ The value of these newer delivery catheters is their radiopaque tip and easy trackability over the Amplatz wire; unfortunately, they do not negotiate every acute angle at the aortic arch. Newer designs are under consideration.

however, we do advise that a fresh balloon be used for stent deployment. Other investigators have elected to use the same balloon and place the stent on the shaft in order to expedite its compression onto the balloon after predilation. We recognize that this may be a cost-saving measure, but it is perhaps not the best area in which to reduce expense. If the delivery balloon has a small hole, the stent will expand improperly, and it could be malpositioned or even migrate, which would be disastrous.

Using a new delivery balloon for the stent also allows us to premount the device once the size has been determined. The advantage of having the stent premounted on a second balloon was emphasized to us in a case where a flow-limiting dissection occurred following balloon dilation. The ability to immediately restore circulation with an already prepared stent averted any potential problem. Oftentimes, the balloon size selected for the stent deployment is one size larger than that used for the angioplasty. Obviously, if a change in balloon size is required, an immediate adjustment can be made.

One comment needs to be made on a perhaps controversial aspect of the technique: the need for predilation. Primary stent implantation has gained favor in other peripheral arteries, and some investigators have used it in the carotid arteries.[3] We agree with the usefulness of this method for ulcerated lesions, where dilation increases the likelihood of releasing embolic material. We have used primary stent implantation in most ulcerated carotid lesions we have treated. However, in the case of significant stenoses, if the narrowing is so tight that there is any chance the stent might be dislodged from the balloon as it traverses the site, we consider it mandatory to predilate. Migration of a stent in the carotid artery would constitute a major complication, which we fortunately have not observed, probably because of this precautionary predilation rule.

Although preventing problems before they occur is resident in every investigator's mind, we have not used either cerebral protection or transcranial Doppler monitoring during these procedures. Initially, we did not believe either was necessary with the direct stick approach, but our 10.9% rate of neurological sequelae in our first 110 patients using both access approaches is a convincing argument in favor of some method to prevent microembolization.

We have also elected not to use pacing wires during carotid stent implantation as some investigators have done. We rely on atropine to quell the baroreceptor response to balloon dilation within the carotid sinus, and it has worked well for us. Of course, blood pressure surveillance must be vigilant and the response to any deviation rapid.

After nearly 200 carotid stent procedures, we are encouraged by the durability of the successfully implanted devices, but the opportunity for serious, debilitating—and lethal—complications is always with us. The techniques we have described are being refined to reduce this potential, but we are in the earliest phases of our experiences with carotid stenting. As our previous report noted, this arterial territory is unique among the peripheral vessels; whereas 200 iliac angioplasties would have elevated any operator to "expert" status, the same cannot be said for the cervical carotid arteries. Extrapolation of experiences and techniques carries us only so far in this area, and any interventionist would recognize that the brain's susceptibility to damage cannot be countered as simply as would be possible in the kidneys or limbs.

The stakes are very high indeed in carotid stenting. If our ongoing patient surveillance shows that carotid stents are as durable as early results would suggest, then we have hope that our efforts will be rewarded. It remains for us to refine our techniques to assure that the safety of the procedure is consistent with carotid endarterectomy so that we may pursue comparison against the gold standard.

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